

Remarks

Upon entry of the amendment, claims 1,3,4 and 11-35 will be pending in the application. Claim 1 has been amended to more distinctly point out and claim the invention. Support for the amendment to claim 1 appears in the specification at, e.g., page 10-17. No new matter has been added.

The Applicants note the withdrawal in the present Office Action of the previous rejections under 35 USC §§112, first paragraph, 102(b), and 103(a).

The claims are newly rejected for overbreadth.

Rejections under 35 USC 112, first paragraph

Claims 1,3, 4, and 11-35 are rejected for overbreadth. The rejection is traversed.

As amended, claim 1, from which the remaining claims subject to the rejection depend, is drawn to a method of treating mucositis in a patient by administering to the patient a topical formulation of a pharmaceutical composition comprising a pharmaceutically effective amount of IL-11. The Examiner acknowledges that the specification is enabled for claims to the treatment of oral mucositis, but contends that the specification does not reasonably supply enablement for the treatment of any kind of mucositis with IL-11 in topical formulations.

Applicants respectfully disagree. MPEP § 2164.01 (citing *United States v. Telectronics, Inc.*, 857 F.2d 778, 8 USPQ2d 1217 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1046 (1989)) states: "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art."

In the present application, the teachings of the specification, coupled with the knowledge of one of ordinary skill in the art, enable one of ordinary skill in the art to practice the full scope of the claimed invention without undue experimentation. Formulations for topical delivery of

IL-11 are taught in detail in the specification at page 12, line 13 to page 15, line 12. These include formulations for oral delivery (see, e.g., the paragraph bridging paragraphs pages 14 and 15).

The specification also provides examples of treating inflammatory bowel disease (Example 1, pages 18, line 13 to page 20, line 20), oral mucositis (Example 2, page 20, line 21, to page 24, line 6); colitis (colonic ulcers) (Example 3, page 24, line 7 to page 25, line 3); mucositis (Example 4, page 25, line 4 to page 26, line 21) and psoriasis (Example 5, page 26, line 22 to page 27, line 9). Using this guidance, the artisan can readily prepare IL-11 containing formulations for topical administration.

With respect to gastrointestinal mucositis, Applicants additionally note that claims drawn to methods of treating inflammatory bowel disease administering a topical formulation interleukin-11 (IL-11) have already issued in US Patent No. 6,126,933, which issued from the parent of the present application.

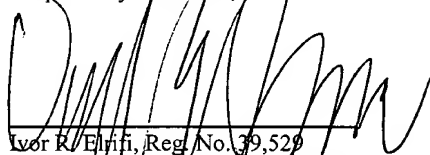
Therefore, Applicants submit that it does not require undue experimentation to practice the full scope of the claimed invention. Reconsideration and withdrawal is requested of the rejection for overbreadth.

Applicants submit that application in condition for allowance, and such action is respectfully requested.

Applicants: Warne *et al.*
U.S.S.N. 09/604,378

Should any questions or issues arise concerning the application, the Examiner is invited and encouraged to contact the undersigned at the telephone number provided below. The Commissioner is authorized to charge any fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 22058-522 CON.

Respectfully submitted,



Ivor R. Elmi, Reg. No. 39,529
David E. Johnson, Reg. No. 41,874
Attorney for Applicants
MINTZ, LEVIN, COHN, FERRIS
GLOVSKY and POPEO, P.C.
One Financial Center
Boston, Massachusetts 02111
Tel: (617) 542-6000
Fax: (617) 542-2241

Dated: October 28, 2003

TRA 1844313v2